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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,824	10/23/2003	Robert Burgermeister	CRD1061CIP2	6326
27777	7590	11/15/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			HOEKSTRA, JEFFREY GERBEN	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 10/691,824	Applicant(s) BURGERMEISTER, ROBERT	
	Examiner Jeffrey G. Hoekstra	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/11/2006 has been entered.
2. The examiner notes the previous Office Action mailed 09/27/2006 is *vacated* as it was erroneously mailed under an incorrect Application Number as indicated in the Interview Summary filed 10/11/2006.

Notice of Amendment

3. In response to the amendment filed on 09/11/2006, amended claim(s) 1, 16, and 26 and canceled claim(s) 39 is/are acknowledged. The current rejections of the claim(s) 1-38 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Claim Objections

4. Claim 15 is objected to because of the following informalities: the term "about" is a relative term that appears to render the claim(s) indefinite. The term "about" is not defined by the claim(s), the specification does not provide a standard for ascertaining

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the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. The thickness of the deflection and retaining ribbons is unclear. Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayzelden et al (US 2002/0165534 A1) in view of Hampton et al (US 4,940,062).

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9. For claims 1, 6, and 26, Hayzelden et al discloses a steerable intravascular device having a deflectable tip, comprising:

- an inner elongated flexible hollow tubing (22) defining a lumen (28) having proximal (26) and distal portions (24);
- a flexible helical coil (82) having proximal and distal ends, the proximal end of said helical coil is attached to the distal portion of the inner elongated flexible hollow tubing (as best seen in Figures 2-3);
- an elongated deflection member (124 and 56) having proximal and distal portions and being slidably disposed within said inner elongated flexible hollow tubing and within said helical coil (as best seen in Figures 5 and 8), the proximal portion of the deflection member being of a cylindrical cross section and the distal portion of said deflection member being flattened or tapered to form a deflection ribbon which extends in a plane (paragraph 43);
- a retaining ribbon (54) having proximal and distal ends, the proximal end of the retaining ribbon is attached to the distal portion of the inner elongated flexible hollow tubing and the retaining ribbon is oriented to extend in a plane which is generally parallel to the plane of the deflection ribbon; and
- an attachment member (50), a rounded epoxy bead, engaging the distal end of the helical coil, the distal portion of the deflection member and the distal end of the retaining ribbon so that longitudinal movement of the deflection member in a distal direction causes the distal end of the helical coil to be deflected in one direction and longitudinal movement of the deflection member in a proximal direction causes the

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distal end of the helical coil to deflect in another opposite direction (as best seen in Figure 2).

10. Hayzelden et al discloses the claimed invention except for an outer elongated flexible tubing surrounding the inner elongated hollow tubing so as to define a passageway between the outer tubing wherein the inner elongated flexible hollow tubing and an inflatable balloon mounted on the outer flexible tubing and communicating with the passageway between the outer tubing and the inner hollow tubing. Hampton et al teaches a steerable intravascular device, a balloon catheter, comprising an outer elongated flexible tubing (46) surrounding an inner elongated hollow tubing (48) so as to define a passageway between the outer tubing wherein the inner elongated flexible hollow tubing and an inflatable balloon (47) are mounted on the outer flexible tubing and communicating with the passageway between the outer tubing and the inner hollow tubing (as best seen in Figures 5-11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the steerable intravascular device as taught by Hayzelden et al, with the catheter configuration as taught by Hampton et al for the purpose of increasing the efficacy of an intravascular device to navigate tortuous vasculature perform a medical procedure.

11. For claims 2, 17, and 27, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein the retaining ribbon and the deflection ribbon are capable of being normally biased in a pre-shaped arcuate configuration to thereby cause the distal end of the helical coil to be normally biased in a curved shape as they are formed from a shape-memory metallic alloy (Hayzelden et al paragraph 43).

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12. For claim 3, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein the proximal portion of said deflection member is of a circular cross section which extends from the proximal portion of the inner flexible tubing to approximately the distal portion of the inner flexible tubing (Hayzelden et al paragraph 43).

13. For claims 4, 7-9, 19-21, 29-31, and 34, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein (a) the proximal end of said retaining ribbon extends from the distal portion of the inner flexible tubing to approximately the distal end of the flexible helical coil (as best seen in Figure 2), (b) the attachment member takes the form of a rounded bead (Hayzelden et al element 50) which contacts the distal end of the helical coil to define a circular surface at the distal end of the coil and the deflection ribbon engages the rounded bead at a location offset from the center of the circular surface of the rounded bead (as best seen in Figures Hayzelden et al 6 and 10), and (c) the distal end of the retaining ribbon engages the rounded bead at a location offset from the center of the circular surface in an opposite direction from the offset location of the deflection ribbon (as best seen in Hayzelden et al Figure 6).

14. For claims 5, 18, and 25, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein the attachment member takes the form of rounded bead (Hayzelden et al element 50).

15. For claim 6, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein the rounded bead is formed with an epoxy material (Hayzelden et al paragraph 30).

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16. For claims 10, 22, and 32, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein the deflection member (Hayzelden et al element 56) and the retaining ribbon are joined to each other within the rounded bead (as best seen in Hayzelden et al Figure 2).

17. For claims 11 and 23, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein the deflection ribbon and the retaining ribbon are formed as a single unitary element (as best seen in Hayzelden et al Figure 2).

18. For claims 12, 24, and 33, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein the deflection ribbon and the retaining ribbon are joined to form a generally U-shaped configuration to thereby provide a predetermined spacing between the deflection ribbon and the retaining ribbon and to maintain the deflection ribbon and the retaining ribbon in planes which are parallel to each other (as best seen in Hayzelden et al Figure 2).

19. For claims 13 and 28, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein flattening an intermediate portion of the deflection member forms the deflection ribbon and flattening the distal portion of the deflection member forms the retaining ribbon (Hayzelden et al paragraph 43).

20. For claims 14 and 35, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein the retaining ribbon is of a thickness that is less than the thickness of the deflection ribbon (Hayzelden et al paragraph 43).

21. For claim 15, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein the deflection ribbon is capable of being a thickness equal

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to 0.002 inches and the retaining ribbon is of a thickness equal to 0.0015 inches (Hayzelden et al paragraph 43).

22. For claim 36, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein the proximal portion of the elongated flexible tubing is coupled to a control handle (Hampton et al element 54) and the elongated deflection member is mounted with the control handle for longitudinal movement (as best seen in Hampton et al Figure 11).

23. For claim 37, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein said control handle includes a movable knob (Hampton et al element 57) which is coupled to the elongated deflection member for longitudinal positioning of the deflection member (as best seen in Hampton et al Figure 11).

24. For claim 38, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein said control handle is coupled to the elongated flexible tubing with a release mechanism (62) so that the handle may be removed from the guidewire (as best seen in Hampton et al Figure 11).

Response to Arguments

25. Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

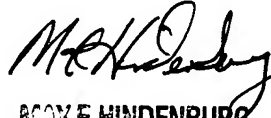
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571) 272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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